

40.32(3) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

40.32(4) Test results shall be kept in units of microcurie or becquerel and maintained for inspection by the Agency.

40.32(5) The following shall be considered evidence that a sealed source is leaking:

- a.* The presence of 0.005 μCi (185 Bq) or more of removable contamination on any test sample.
- b.* Leakage of 0.001 μCi (37 Bq) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.
- c.* The presence of removable contamination resulting from the decay of 0.005 μCi (185 Bq) or more of radium.

40.32(6) The licensee shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this chapter.

40.32(7) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 40.102(136C).

641—40.33 to 40.35 Reserved.

SURVEYS AND MONITORING

641—40.36(136C) Surveys and monitoring—general.

40.36(1) Each licensee or registrant shall make, or cause to be made, surveys that:

- a.* Are necessary for the licensee or registrant to comply with this chapter; and
- b.* Are necessary under the circumstances to evaluate:
 - (1) Radiation levels; and
 - (2) Concentrations or quantities of radioactive material; and
 - (3) The potential radiological hazards that could be present.

40.36(2) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured except when a more frequent interval is specified in another applicable part of these rules or a license condition.

40.36(3) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 40.15(136C), with other applicable provisions of these rules, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

- a.* Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and
- b.* Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

40.36(4) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

641—40.37(136C) Conditions requiring individual monitoring of external and internal occupational dose. Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this chapter. As a minimum:

40.37(1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

- a.* Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 40.15(1); and
- b.* Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in 40.21(136C) or 40.22(136C); and
- c.* Individuals entering a high or very high radiation area.
- d.* Individuals working with medical fluoroscopic equipment.

40.37(2) Each licensee or registrant shall monitor, to determine compliance with 40.18(136C), the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

- a.* Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and
- b.* Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.05 rem (0.5 mSv).

40.37(3) Location of individual monitoring devices. Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 40.37(136C) wear individual monitoring devices as follows:

- a.* An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded portion of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar);
- b.* An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman shall be located at the waist under any protective apron being worn by the woman;
- c.* An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with 40.15(136C) shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;
- d.* An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 40.15(136C), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

641—40.38 to 40.41 Reserved.

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

641—40.42(136C) Control of access to high radiation areas.

40.42(1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

- a.* A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

- b.* A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or
- c.* Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

40.42(2) In place of the controls required by 40.42(1) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

40.42(3) The licensee or registrant may apply to the Agency for approval of alternative methods for controlling access to high radiation areas.

40.42(4) The licensee or registrant shall establish the controls required by 40.42(1) and 40.42(3) in a way that does not prevent individuals from leaving a high radiation area.

40.42(5) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation provided that:

- a.* The packages do not remain in the area longer than three days; and
- b.* The dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

40.42(6) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this chapter and to operate within the ALARA provisions of the licensee's radiation protection program.

40.42(7) The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 641—40.42(136C) if the registrant has met all the specific requirements for access and control specified in other applicable chapters such as 641—Chapter 45 for industrial radiography, 641—Chapter 41 for X-rays in the healing arts, and 641—Chapter 41 for particle accelerators.

641—40.43(136C) Control of access to very high radiation areas.

40.43(1) In addition to the requirements in 40.42(136C), the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rad (5 Gy) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic X-ray systems are the only source of radiation, or to non-self-shielded irradiators.

40.43(2) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 40.43(1) if the registrant has met all the specific requirements for access and control specified in other applicable chapters such as 641—Chapter 45 for industrial radiography, 641—Chapter 41 for X-rays in the healing arts, and 641—Chapter 41 for particle accelerators.

641—40.44(136C) Control of access to very high radiation areas—irradiators.

40.44(1) This rule applies to licensees with sources of radiation in non-self-shielded irradiators. This rule does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

40.44(2) Each area in which there may exist radiation levels in excess of 500 rad (5 Gy) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

a. Each entrance or access point shall be equipped with entry control devices which:

(1) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

(2) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(3) Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 0.1 rem (1 mSv) in 1 hour.

b. Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by 40.44(2) “*a*”:

(1) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(2) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

c. The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source’s shielded storage container:

(1) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(2) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

d. When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

e. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of 40.44(2) “*c*” and 40.44(2) “*d*.”

f. Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

g. Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

h. Each area shall be checked by a radiation measurement to ensure that, prior to the first individual’s entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour.

i. The entry control devices required in 40.44(2)“a” shall be tested for proper functioning. See 40.89(136C) for record-keeping requirements.

(1) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(2) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(3) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

j. The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

k. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.

40.44(3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of 40.44(2) which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of 40.44(2), such as those for the automatic control of radiation levels, may apply to the Agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in 40.44(2). At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

40.44(4) The entry control devices required by 40.44(2) and 40.44(3) shall be established in such a way that no individual will be prevented from leaving the area.

641—40.45 to 40.47 Reserved.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT
INTERNAL EXPOSURE IN RESTRICTED AREAS

641—40.48(136C) Use of process or other engineering controls. The licensee shall use, to the extent practical, process or other engineering controls, such as containment or ventilation, to control the concentrations of radioactive material in air.

641—40.49(136C) Use of other controls. When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

40.49(1) Control of access; or

40.49(2) Limitation of exposure times; or

40.49(3) Use of respiratory protection equipment; or

40.49(4) Other controls.

641—40.50(136C) Use of individual respiratory protection equipment.

40.50(1) If the licensee uses respiratory protection equipment to limit intakes pursuant to 40.49(136C):

a. Except as provided in 40.50(1), the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

b. If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

c. The licensee or registrant shall implement and maintain a respiratory protection program that includes:

(1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

(2) Surveys and bioassays, as appropriate, to evaluate actual intakes; and

(3) Testing of respirators for operability immediately prior to each use; and

(4) Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and record keeping; and

(5) Determination by a physician prior to initial fitting of respirators, and either every 12 months thereafter, or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.

d. The licensee shall issue a written policy statement on respirator usage covering:

(1) The use of process or other engineering controls, instead of respirators; and

(2) The routine, nonroutine, and emergency use of respirators; and

(3) The length of periods of respirator use and relief from respirator use.

e. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

f. The licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

40.50(2) When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to 40.49(136C), provided that the following conditions, in addition to those in 40.50(1), are satisfied:

a. The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the multiple defined in the preceding sentence is inconsistent with the goal specified in 40.49(136C) of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

b. The licensee shall obtain authorization from the Agency before assigning respiratory protection factors in excess of those specified in Appendix A. The Agency may authorize a licensee to use higher protection factors on receipt of an application that:

- (1) Describes the situation for which a need exists for higher protection factors, and
- (2) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

40.50(3) In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

40.50(4) The licensee shall notify the agency in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either 40.50(1) or 40.50(2). The agency may impose restrictions in addition to those listed in these rules in order to limit individual exposures.

641—40.51 to 40.54 Reserved.

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

641—40.55(136C) Security and control of licensed or registered sources of radiation.

a. The licensee or registrant shall secure licensed or registered radioactive material from unauthorized removal or access.

b. The licensee or registrant shall maintain constant surveillance and use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in an unrestricted area and that is not in storage.

c. The registrant shall secure registered radiation machines from unauthorized removal.

d. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

641—40.56(136C) Control of sources of radiation not in storage. Rescinded IAB 4/8/98, effective 7/1/98.

641—40.57 to 40.59 Reserved.

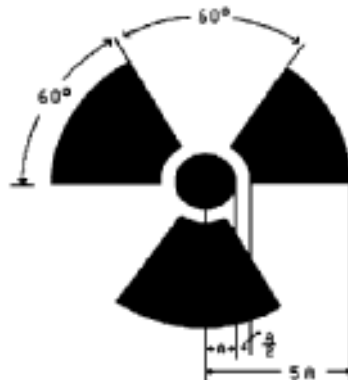
PRECAUTIONARY PROCEDURES

641—40.60(136C) Caution signs.

40.60(1) Standard radiation symbol. Unless otherwise authorized by the Agency, the symbol prescribed by this rule shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.



40.60(2) Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of 40.60(1), licensees are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

40.60(3) Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this chapter, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

641—40.61(136C) Posting requirements.

40.61(1) Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA".

40.61(2) Posting of high radiation areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA".

40.61(3) Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA".

40.61(4) *Posting of airborne radioactivity areas.* The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, AIRBORNE RADIOACTIVITY AREA” or “DANGER, AIRBORNE RADIOACTIVITY AREA”.

40.61(5) *Posting of areas or rooms in which licensed or registered material is used or stored.* The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding ten times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL(S)” or “DANGER, RADIOACTIVE MATERIAL(S)”.

641—40.62(136C) Exceptions to posting requirements.

40.62(1) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

a. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this chapter; and

b. The area or room is subject to the licensee’s or registrant’s control.

40.62(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 40.61(136C) provided that the patient could be released from confinement pursuant to 641—41.29(136C).

40.62(3) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.

40.62(4) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

641—40.63(136C) Labeling containers and radiation machines.

40.63(1) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL”. The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

40.63(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

40.63(3) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

641—40.64(136C) Exemptions to labeling requirements. A licensee is not required to label:

40.64(1) Containers holding licensed materials in quantities less than the quantities listed in Appendix C; or

40.64(2) Containers holding licensed material in concentrations less than those specified in Table III of Appendix B; or

40.64(3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this chapter; or

40.64(4) Containers when they are in transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation;² or

² Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.